REMARKS

This paper is responsive to the non-final Office Action mailed June 23, 2009. Entry of these amendments and remarks, and reconsideration and allowance of the application, is earnestly requested.

Status of the claims

Claims 1-11, 13, 15, 16, and 18-30 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Li et al., U.S. Pat. No. 6,836,529 (hereinafter "Li") in view of Weil et al., U.S. Pat. No. 6,821,254 (hereinafter "Weil").

The applied references

Li relates primarily to cardiac-gated imaging. The only mentions of respiratory monitoring in Li are in the abstract ("A system and method of diagnostic imaging with reduced x-ray exposure to the scan subject during scanning includes acquiring a set of cardiac signals or other motion (cardiac mechanical motion or respiratory motion) related signals and determining and imaging profile therefrom.") and at col. 5 lines 44-47 ("While EKG signals have heretofore been described as a means of developing an imaging profile, other data signals may be acquired and analyzed to develop an imaging profile including respiratory data signals.").

Li does not disclose any system or method by which the "respiratory data signals" can be generated. Indeed, Li provides no information whatsoever about how to perform respiratory monitoring. For example, the "respiratory data signals" of Li could be acquired using a a mechanical strain gauge or other mechanical sensor.

Weil discloses (Fig. 3) a monitor designed to detect cardiac arrest (defined as the heart rate being below 20 beats/minute) or asphyxial arrest (defined as the respiratory rate being below four beats/minute). Toward this end, a 35 kHz a.c. current is applied to the patient via electrodes (12, 14) and the voltage response is detected and any common mode component removed by differential amplifier (52), and the 35 kHz carrier removed by demodulation via RMS-DC converter (54). The resulting signal is essentially an impedance (technically impedance is V/I, but the current is kept constant so the output of the converter (54) varies with impedance).

The resulting signal is used (Weil Fig. 4) to detect cardiac pulse rate and respiratory rate by calculating the fast Fourier transform (FFT). Weil col. 4 lines 1-9. Corresponding cardiac and respiratory impedances are also determined by bandpass filtering. Col. 4 lines 9-14. Weil Table 1 is then consulted to determine whether the patient is in cardiac and/or asphyxial arrest. Comparison of the cardiac impedance with a calibration curve (Fig. 7) can yield aortic pressure. Col. 5 lines 30-33. Comparison of the respiratory impedance with a calibration curve (Fig. 8) can yield tidal (breathing) volume. Col. 5 lines 33-36.

Weil does not disclose or fairly suggest any approach for determining the respiratory phase or respiratory state from its voltage information.

Weil also does not disclose or fairly suggest integration of its arrest monitor with an electrocardiograph. Indeed, Weil teaches away from this by disclosing a *different* cardiac monitor, namely an active cardiac monitor that operates on the measured thoracic impedance, not on an electrocardiographic signal.

Claim amendments

Each of claims 6, 8, and 11 is placed into independent form including all limitations of canceled base claim 1. Dependent claims 2-5, 9, 10, and 30 are placed off claim 8 with suitable formal amendments for consistency.

Claim 26 is placed into independent form including all limitations of canceled base claim 13. Claims 15, 16, 19, 21-25, 27, and 29 are placed off claim 26 with suitable formal amendments for consistency. Claims 19 and 20 are amended to recite electrocardiographic data. Claim 27 is amended to recite gating based on the extracted time varying respiratory cycle phase function.

Independent claim 18 and dependent claim 28 are canceled.

The claims present patentable subject matter and should be allowed

Claim 6 recites (among other elements) an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes; and a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter, the monitor including a differentiator that computes a time derivative of the time-varying electrical parameter.

Li does not disclose or fairly any particular apparatus for extracting a time-varying respiration characteristic, much less the combination of an electrical meter and monitor recited in claim 6.

Weil discloses an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes. However, Weil does *not* disclose or fairly suggest a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter, *the monitor including a differentiator that computes a time derivative of the time-varying electrical parameter*.

Weil employs wholly different processing, namely removal of the mean and trend and alternative pathways of (i) bandpass filtering or (ii) FFT and extraction of respiratory rate. See Weil Fig. 4. There is no disclosure or fair suggestion in Weil of including a differentiator that computes a time derivative of the time-varying electrical parameter.

In this regard, it should be noted that element (52) shown in Weil Fig. 3 is a differential amplifier (52) (Weil col. 3 line 55). A differential amplifier is typically used to remove the common-mode signal component and/or to provide pre-amplification. The transfer function is of the form $V_o=A_d(V_{in}^{+}-V_{in}^{-})$ where V_{in}^{+} and V_{in}^{-} are the signals at terminals (12, 14) (or vice versa) and A_d is the differential amplifier gain. The differential amplifier (52) is not a differentiator, and does not compute a time derivative of anything.

Claim 7 depends from claim 6, and recites the time-varying electrical parameter includes a time-varying resistance, the differentiator computes a first derivative, and the monitor further includes a respiration state processor that computes the respiration parameter as one of: inhaling corresponding to a positive time derivative of the time varying resistance; exhaling corresponding to a negative time derivative of the time varying resistance, and a breath-hold state corresponding to a substantially zero time derivative of the time-varying resistance.

Weil does not disclose or fairly suggest a differentiator that computes a first derivative. Moreover, Weil does not disclose or fairly suggest a respiration state processor that computes the respiration parameter as one of: inhaling corresponding to a positive time derivative of the time varying resistance; exhaling corresponding to a negative time derivative of the time varying resistance, and a breath-hold state corresponding to a substantially zero time derivative of the time-varying resistance. More fundamentally, Weil does not provide the insight that one *can* relate the sign of a time-varying resistance with respiration states selected from the group consisting of inhaling, exhaling, and breath-hold. Li cannot remedy this deficiency of Weil, at least because Li also does not provide this insight.

In sum, it is respectfully submitted that claims 6 and 7 present patentable subject matter and Applicants therefore respectfully request allowance of claims 6 and 7.

Claim 8 recites (among other elements) an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes; and a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter, the monitor including a respiratory cycle phase processor that estimates a respiratory cycle phase based on the time varying electrical parameter.

Li does not disclose or fairly any particular apparatus for extracting a time-varying respiration characteristic, much less the combination of an electrical meter and monitor recited in claim 8.

Weil discloses an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes. However, Weil does *not* disclose or fairly suggest a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter, *the monitor including a respiratory cycle phase processor that estimates a respiratory cycle phase based on the time varying electrical parameter*. Indeed, the Office Action does not allege that Weil discloses this feature, stating only that Weil discloses "[a]n analyzing circuit [that] determines the average amplitude and frequency of signals representing heartbeats and those representing respiration." (Office Action page 3).

Weil discloses performing bandpass filtering to identify a respiratory impedance (Fig. 4), but does not disclose or fairly suggest estimating a respiratory cycle phase based on the output of the bandpass filter. Weil also discloses employing a fast Fourier transform (FFT) to determine respiratory rate (Fig. 4), and also discloses computing peak-to-peak amplitude of the signal (Weil col. 4 lines 5-11). The respiratory impedance amplitude is used in Weil for determining tidal volume as per Weil Fig. 8 and col. 5 lines 33-37. None of this discloses or fairly suggests a monitor including a respiratory cycle phase processor that estimates a *respiratory cycle phase* based on the time varying electrical parameter.

Claim 4 depends from claim 8, and recites the electrical meter includes: a voltage pulse generator that applies a voltage pulse train to the electrode pair; and an ammeter that measures an electrical current flowing between the electrode pair responsive to the applied voltage pulse train.

As already noted, Li does not disclose any sort of electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes.

Weil cannot remedy this deficiency of Li respective to claim 4, because Weil discloses a materially different electrical meter in which a 1 milliampere *electrical current is applied*, and the *voltage is measured*. Li col. 3 lines 5-18. The applied *current* is kept constant, so that the measured voltage corresponds to

resistance. *Id.* Thus, Weil discloses the diametrically opposite configuration as compared with claim 4.

In sum, it is respectfully submitted that claims 2-5, 8-10, and 30 present patentable subject matter and Applicants therefore respectfully request allowance of claims 2-5, 8-10, and 30.

Claim 11 recites a diagnostic imaging scanner that acquires imaging data of a subject in an examination region; a reconstruction processor that reconstructs the acquired imaging data into an image representation; a pair of electrodes adapted to externally contact a thoracic region of the subject; *an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes*; a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter; and *an electrocardiograph that measures electrocardiographic data of the subject using at least the pair of electrodes.*

Li discloses using an electrocardiograph (ECG) to acquire electrocardiographic data using a pair of electrodes for cardiac gating of diagnostic imaging. However, Li does not disclose or fairly suggest the *combination* of such an ECG with an electrical meter that measures a time-varying electrical parameter across the electrode pair by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes.

The combination of claim 11 is disclosed in the present application:

> For cardiac computed tomography imaging, an electrocardiograph **66** suitably monitors cardiac cycling simultaneously with monitoring of the respiratory cycle using the electrodes pair **30, 32**. In a preferred embodiment, the impedance meter **34** measures a pulse-modulated signal with a pulse frequency substantially higher than the heart rate. Hence, the impedance measurement signal and the electrocardiographic signal are readily decoupled by frequency selective filtering.

Present application page 5 lines 3-8.

> To remove the high-frequency signal components produced by the pulse generator **72**, a lowpass filter **82** is suitably applied prior to electrocardiographic measurement. Although a separate filtering component **82** is shown in FIGURE 2, the filter is optionally omitted if a frequency response of the electrocardiograph **66** is such that the electrocardiograph **66** does not respond to signal components at the pulse train frequency.
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> Present application page 6 lines 2-7.

In contrast, Weil combines respiratory and cardiac monitoring by employing a *different* cardiac monitor. Specifically, Weil's cardiac monitor analyzes the *impedance* measured responsive to the 1 millampere applied current to determine the pulse rate. In particular, Weil teaches that the *high* frequency (1.5-20 Hz) *impedance* component corresponds to cardiac impedance (Fig. 4) and the *low* frequency (0.1-2 Hz) impedance component corresponds to the respiratory impedance.

Weil fails entirely to recognize that the intrinsic *electrocardiographic (ECG)* signal can be measured using the *same* electrodes, by *low-pass* filtering the signal, e.g. using the low-pass filter (82) as taught in the present application. Without this insight, there is no motivation to combine the ECG of Li with the monitor of Weil to reach claim 11.

In sum, it is respectfully submitted that claim 11 presents patentable subject matter and Applicants therefore respectfully request allowance of claim 11.

Claim 26 recites acquiring imaging data of a medical imaging patient; reconstructing at least a part of the acquired imaging data into an image representation; externally contacting a thoracic region of the patient with the pair of external electrodes; *measuring a time-varying electrical parameter across the external electrodes pair during the acquiring of imaging data*, the measuring including applying one of a voltage and a current to the external electrodes pair, measuring the other of voltage and current responsive to the applying, and computing the time-varying electrical parameter based on the applied and measured quantities; and computing a time-varying respiration characteristic based on the measured time-

varying electrical parameter wherein the computing of a time-varying respiration characteristic from the time-varying electrical parameter includes *computing a time varying respiratory cycle phase function based on the time varying electrical parameter*.

Li generically discloses gating using "respiratory data signals", but does not disclose or fairly suggest measuring a time-varying electrical parameter across the external electrodes pair during the acquiring of imaging data and computing a time varying respiratory cycle phase function based on the time varying electrical parameter.

Weil discloses measuring respiratory impedance and respiratory rate by applying a current and measuring a voltage (thus measuring impedance for a constant applied current of 1 milliampere). However, Weil does *not* disclose or fairly suggest *computing a time varying respiratory cycle phase function based on the time varying electrical parameter*. Rather, Weil discloses performing bandpass filtering to identify the respiratory impedance and FFT to determine respiratory rate (Fig. 4), and also discloses computing peak-to-peak amplitude of the signal (Weil col. 4 lines 5-11). None of this discloses or fairly suggests computing a time varying respiratory cycle phase function based on the time varying electrical parameter.

Claim 27 recites gating the acquiring of imaging data based on the extracted time varying respiratory cycle phase function. One cannot gate the imaging based on Weil's respiratory rate (which is an averaged quantity such as that generated by applying an FFT to several cycles of respiration). One might gate the imaging using Weil's respiratory impedance – however, this approach would be substantially inferior to that of claim 27, since gating based on respiratory impedance would be disconnected from the respiration physiology (e.g., breath inhalation, breath exhalation, breath holds, or so forth).

Claim 22 recites the computing of a time-varying respiratory cycle phase function based on the time-varying electrical parameter includes *determining a respiration state based on a temporal slope of the time-varying electrical parameter*. The Office Action does not allege that either Li or Weil disclose this subject matter, and Applicants find no suggestion in either reference or their combination of

determining a respiration state based on a temporal slope of the time-varying electrical parameter.

More fundamentally, Weil does not provide the insight that one *can* relate the temporal slope of a time-varying electrical parameter with a respiration state. Li cannot remedy this deficiency of Weil, at least because Li also does not provide this insight.

Claim 23 recites the computing of a time-varying respiratory cycle phase function based on the time-varying electrical parameter includes selecting a respiration state based on a temporal slope of the time-varying electrical parameter, the respiration state being selected as one of: inhaling corresponding to a positive temporal slope; exhaling corresponding to a negative temporal slope; and a breath-hold state corresponding to a generally horizontal slope.

As already noted herein with reference to claim 22, Applicants find no disclosure or fair suggestion in the proposed combination of Li and Weil of *determining a respiration state based on a temporal slope of the time-varying electrical parameter*, much less of the further recitation of *the respiration state being selected as one of: inhaling corresponding to a positive temporal slope; exhaling corresponding to a negative temporal slope; and a breath-hold state corresponding to a generally horizontal slope*.

In sum, it is respectfully submitted that claims 15, 16, 19-27, and 29 present patentable subject matter and Applicants therefore respectfully request allowance of claims 15, 16, 19-27, and 29.

CONCLUSION

For the reasons set forth above, it is submitted that claims 2-11, 15, 16, 19-27, 29, and 30 as set forth herein (that is, all claims) present patentable subject matter and meet all statutory requirements. Accordingly, Applicants respectfully request reconsideration and allowance of all claims.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at 216.363.9000.

Respectfully submitted,

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